

REMARKS

This is responsive to the Office Action of January 27, 2006. Claims 1-24 are pending in the application.

In this Office Action, Examiner has objected to the drawings under 37 CFR 1.84(p)(5) for failing to include numeral “38” of “clip structure 38” discussed on page 18, lines 14-15 of the specification. In view thereof, Applicant’s representative submits herewith a replacement drawing sheet including Figs. 8a and 8b with Fig. 8b illustrating numeral 38 of clip structure 38.

In addition, Examiner has objected to the specification and claims 4 and 9 over certain informalities. Applicant’s representative has attended to these informalities by deleting --come-- and inserting “dome” on page 17, line 10 of the specification, by inserting a missing period at the end of claim 4, and by inserting “with” after “coupled” in claim 9.

Also, claims 4, 6, and 8 currently stand rejected under 35 U.S.C. §101 because the claimed invention is allegedly directed to non-statutory subject matter. In view thereof, dependent claims 4, 6, and 8 have been amended according to Examiner’s suggestions.

Finally, claims 9-11, 13-17, and 19-21 currently stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,727,569 to Benetti et al. (“the Benetti patent”); Claims 1-3, 5, and 8 currently stand rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,957,977 to Melvin (“the Melvin patent”) in view of the Benetti patent; and claims 23 and 24 currently stand rejected under 35 U.S.C. §103(a) as being obvious over the Benetti patent in view of the Melvin patent.

In view of the rejections, independent claims 1 and 9 have been amended to more clearly define Applicant's invention. Specifically, claims 1 and 9 each now recite that the heart-mounted structure for assisting the operation of a natural heart comprises an assistive heart-actuating dome structure that assists actuation of the heart. Support for the amendments to these claims can be found throughout the specification and, more specifically, at least at page 1, lines 2-4; page 10, lines 17-23; page 17, line 17 to page 18, line 18; and Figs. 1a-1d, 8a, and 8b.

In view of the foregoing amendments, as well as the following remarks, Applicant respectfully submits that this application is in complete condition for allowance and requests reconsideration of the application in this regard.

35 U.S.C. §102 -- Rejections of Claims 9-11, 13-17, and 19-21

Examiner has rejected claims 9-11, 13-17, and 19-21 under 35 U.S.C. §102(b) as being anticipated by the Benetti patent.

In rejecting the claims over the Benetti patent, Examiner states that this reference discloses a heart-mounted structure including a dome structure (1) having openings (2 and 9) and a bottom surface (6) shaped to conform to the surface of the heart (column 3, lines 9-11). Because the bottom surface has at least one opening (2) that stably affixes the dome structure (1) to the heart surface using negative pressure, the dome structure is configured so that it is capable of being coupled with a basal surface of a ventricular portion of the heart, and proximate the opening (2), is configured so that it is capable of interfacing with an atrial chamber of the heart. See Paragraph 7 of the Office Action.

Further concerning the Benetti patent, this reference appears to pertain to devices and techniques which use a negative (suction) pressure or vacuum, applied through a surgical instrument, to fix the position of a portion of the surface of a beating heart so that a surgical procedure can be more easily performed. The devices apply a negative pressure at several points on the outer surface of the heart such that a portion of the heart is fixed in place by the suction imposed through the surgical instrument. See, e.g., abstract; col. 1, lines 46-53; col. 2, lines 51-54; col. 4, lines 38-40; and Figs. 1-3.

It is well established that "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). For the following reasons, the Benetti patent clearly fails to teach each and every element of Applicant's heart-mounted structure for assisting the operation of a natural heart which comprises an assistive heart-actuating dome structure that assists actuation of the heart as recited in independent claim 9.

Applicant's claimed heart-mounted structure assists the operation, i.e. assists the actuation, of a natural heart. More specifically, the heart-mounted structure includes an assistive heart-actuating dome structure that assists actuation of the heart, the dome structure configured for being coupled with a basal surface of a ventricular portion of the heart. Such structure is an assistive heart-actuating dome structure insofar as it assists the actuation, or beating, of a natural heart. In stark contrast to Applicant's assistive heart-actuating dome structure, the Benetti patent teaches a simple dome structure (1) that merely fixes the position of a portion of the surface of a

beating heart, via suction, so that a surgical procedure can be more easily performed. *See, e.g.,* abstract; col. 1, lines 46-53; col. 2, lines 51-54; col. 4, lines 38-40; and Figs. 1-3. This dome structure (1) clearly fails to assist the actuation, or beating, of a natural heart. Therefore, it cannot be an assistive heart-actuating dome structure that assists actuation of the heart as required by Applicant's claim 9.

For all of the above reasons, the Benetti patent does not teach, or suggest, Applicant's independent claim 9, or any of its dependent claims.

Section 103 -- Rejections of Claims 1-3, 5, and 8

Claims 1, 3, 5, and 8 are rejected under § 103(a) as being unpatentable over the Melvin patent in view of the Benetti patent. Applicant's distinguishing comments set out above with respect to the Benetti patent apply equally to the §103 rejection.

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). There is clearly no such teaching in the cited references. In fact, the obviousness rejection under §103 appears to be merely a gathering of unrelated pieces of art in an attempt (certainly hindsight) to simply list all the elements, regardless of the functions of the gathered elements.

Examiner cites the Melvin patent for the purpose of supplying the actuating element recited in claim 1. The Melvin patent, in fact, is specifically discussed in Applicant's specification as disclosing a suitable actuating element for anchoring to the assistive heart-

actuating dome structure. However, there simply is no motivation to combine the actuating element of the Melvin patent with the simple dome structure of the Benetti patent. As already discussed above, the dome structure (1) of the Benetti patent merely fixes the position of a portion of the surface of a beating heart so that a surgical procedure can be more easily performed and, clearly, fails to assist the actuation, or beating, of a natural heart. Accordingly, one skilled in the art would not look to combine the actuating element of the Melvin patent, which actuates the natural heart, with the dome structure of the Benetti patent, which does not assist heart actuation, to arrive at Applicant's invention as recited in claim 1. In fact, not only would one of ordinary skill in the art not combine the references, Applicant submits that the combination of the respective structures of the Benetti and Melvin patents would fail to provide an actual working actuation system. Thus, the combination of the references does not render obvious Applicant's invention as recited in claim 1.

Furthermore, even assuming *arguendo* that one skilled in the art would combine the Benetti patent and the Melvin patent, the combination of the references still fails to teach or suggest Applicant's invention as recited in claims 1 and 9. As fully discussed above, the Benetti patent fails to teach or suggest Applicant's assistive heart-actuating dome structure that assists actuation of the heart. The Melvin patent fails to fill this teaching void. Accordingly, the rejection of claims 1, 3, 5, and 8 over the combination of the Melvin and Benetti patents is in error.

In addition, Applicant's representative further submits that the Benetti patent, which is directed to devices for assisting in surgical procedures performed on the heart, simply

has no relevance, i.e. is non-analogous, to Applicant's claimed heart-mounted structure that assists the operation, i.e. assists the actuation, of a natural heart. And, thus, as a matter of law, the Benetti patent is unavailable as prior art.

For all of the above reasons, the combination of the Benetti patent and the Melvin patent does not render obvious Applicant's independent claim 1, or any of its dependent claims.

Section 103 -- Rejections of Claims 23 and 24

Claims 23 and 24 are rejected under § 103(a) as being unpatentable over the Melvin patent in view of the Benetti patent.

For all of the aforementioned reasons, Applicant further respectfully submits that dependent claims 23 and 24, likewise, are allowable over the combination of the Melvin and Benetti patents, such claims being in condition for allowance.

Conclusion

As a result of the remarks given herein, Applicant submits that the rejections of the pending claims have been overcome. Therefore, Applicant respectfully submits that this case is in condition for allowance and requests allowance of the pending claims.

If Examiner believes any detailed language of the claims requires further discussion, Examiner is respectfully asked to telephone the undersigned attorney so that the matter may be promptly resolved. Applicants also have submitted all fees believed to be necessary herewith.

Should any additional fees or surcharges be deemed necessary, Examiner has authorization to charge fees or credit any overpayment to Deposit Account No. 23-3000.

Respectfully submitted,
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